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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,328	09/21/2000	Gary W. Pace	121-112	8438

7590

07/02/2003

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/02/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/667,328

Applicant(s)

PACE ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 39-41, 43, 44, 48-51, 53 and 54 is/are allowed.
- 6) ☒ Claim(s) 16-23, 25-27, 29-38, 42, 45, 47 and 52 is/are rejected.
- 7) ☒ Claim(s) 24 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Receipt of Request for Continued Examination, Amendment C, Petition, and Information Disclosure received on April 11, 2003 is acknowledged. Claims 16-54 are included in the prosecution of this application.

#### ***Information Disclosure Statement***

The information disclosure statement submitted April 11, 2003 has been placed in the application file, but the references that have not been initialed have not been considered as to the merits since an English abstract or translation has not been submitted. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 20, 23, 34, 36, 42, 47, and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Claims 23 and 36 recite campothecin, a derivative of campothecin, paclitaxel, a derivative of paclitaxel" which is indefinite since it is unclear what this encompasses. The

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applicant is requested to define "derivative" of the respective drug and cite support for the definition. Applicant's specification merely recites derivative and one of ordinary skill would not be clear of what this encompasses.

Claims 42 and 52 recite "ethyl alcohol" as a non-aqueous hydrophobic liquid which is unclear since ethyl alcohol is a hydrophilic solvent.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claims 20, 34, 47 recites the broad recitation low molecular weight alcohol and polyhydric alcohol respectively and the claim also recites ethanol and glycerol/glycol respectively which is the narrower statement of the range/limitation. Additionally claims 18 and 45 recite "polyethylene glycol" which is the broad limitation and specific PEG surfactants which is the narrow part of the claim. Note that "polyethylene glycol" is recited twice in the claim. Applicant is requested to delete one.

### ***Claim Objections***

Claims 24 and 28 are objected to for being dependent on a rejected claim and would be allowable if rewritten to include all of the limitations of the base claim and any intervening claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 16-22, 25-27, 29-35, 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,527,638.**

GB discloses a niclosamide suspension. The formulation contains niclosamide (particle size of 2 to 20 microns) in sesame oil, polyoxyethylene-sorbiatn monooleate, and 10% n-butanol. See examples. Additionally, lecithin is utilized in the examples. The suspension is administered to an animal.

Note that the limitation “wherein upon addition of said composition...” is intended use since the claim does not require the addition of the fluid aqueous medium. Furthermore, this limitation is inherent since the oil suspension will inherently form droplets when combined with an aqueous medium and since GB teaches the administration of the formulation to an animal; GB anticipates the instant invention.

#### ***Allowable Subject Matter***

Claims 23, 42, 47, and 52 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 39-41, 43, 44, 48-51, 53 and 54 are allowable over the prior art since prior art does not teach the instant drug in a hydrophobic carrier medium wherein the drug is in an undissolved form.

#### ***Conclusion***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

June 26, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER